

ABSTRACT OF THE INVENTION

A solid-phase immunoassay for 6-keto-Prostaglandin $F_{1\alpha}$, the stable hydrolysis product of prostacyclin (Prostaglandin I₂) is disclosed. Prostacyclin, a potent vasodilator with anti-platelet and anti-proliferative properties is an effective treatment for primary pulmonary hypertension and pulmonary arterial hypertension associated with scleroderma and scleroderma-like syndrome. Levels of 6-keto-Prostaglandin $F_{1\alpha}$ can be directly correlated with levels of prostacyclin. Therefore, 6-keto-Prostaglandin $F_{1\alpha}$ has become the indicator of choice to measure prostacyclin levels. The single step immunoassay for 6-keto-Prostaglandin $F_{1\alpha}$ uses the bioluminescent protein, aequorin as a label. Analyte-label conjugates were constructed by linking the carboxyl group of 6-keto-Prostaglandin $F_{1\alpha}$ and lysine residues of aequorin by chemical conjugation methods. The binding properties of 6-keto-Prostaglandin $F_{1\alpha}$ towards its antibody and the bioluminescent properties of aequorin are retained in the conjugate. The concentration of 6-keto-Prostaglandin $F_{1\alpha}$ after extraction from plasma shows good correlation with the concentration of 6-keto-Prostaglandin $F_{1\alpha}$ obtained without prior extraction of the same plasma sample. The assay allows the measurement of 6-keto-Prostaglandin $F_{1\alpha}$ directly in plasma without any pre-treatment of the samples, which results in a much simpler method with a faster assay time.